# APPROVAL ORDER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2004

VISX, Inc.
c/o Alan F. Russell, Ph.D.
Vice President, Regulatory and Clinical Affairs
3400 Central Expressway
Santa Clara, CA 95051

Re: P930016/S17
STAR S4™ Excimer Laser System with Variable Spot Scanning (VSS™)
and WaveScan WaveFront® System
Filed: May 12, 2004
Amended: May 12, July 30, October 14 and November 22, 2004

Dear Dr. Russell:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the VISX STAR S4™ Excimer Laser System with VSS™ and WaveScan WaveFront® System. This device uses a 6.00 mm optical zone, a 9.00 mm treatment zone, and is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK):

- for the reduction or elimination of hyperopia and hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 D;
- in patients 21 years of age or older; and
- in patients with documented evidence of a change in manifest refraction of no more than 1.0 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

The PMA supplement is approved. You may begin commercial distribution of the device as modified in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

The following restrictions on the use, labeling, promotion, and advertising of these devices are applicable to you, as well as any device purchasers and users. You must notify the purchasers and users of these restrictions and include them in your training programs.

1. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery including laser system calibration and operation, may use the devices as approved in this order.

2. Prospective patients, as soon as they express an interest in wavefront-guided LASIK for hyperopic astigmatism and prior to undergoing surgery, must receive from the treatment provider the Patient Information Booklet (as described in your final submission to this PMA supplement).

3. Prior to undergoing surgery, prospective patients must be informed of the alternatives for correcting their hyperopia including eyeglasses, contact lenses, and other refractive surgeries.

4. Comparison of the safety and effectiveness of this laser with any other method of refractive correction in the promotion and advertising materials is prohibited. This prohibition is based on the fact that the data submitted for PMA supplemental approval of the VISX STAR S4™ Excimer Laser System with VSS™ and WaveScan WaveFront® System do not compare the clinical outcomes of these devices with any other method of refractive correction. Such comparisons of safety and effectiveness are misleading and would misbrand your laser in accordance with section 502(a) of the act. All promotion and advertising for these devices must include the following information on indications, risks and benefits:

    a. Approval of the premarket approval application supplement is for the VISX STAR S4™ Excimer Laser System with VSS™ and WaveScan WaveFront® System to perform wavefront-guided LASIK treatments for the reduction or elimination of hyperopia and hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 D in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 1.0 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

    b. Wavefront-guided LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries.

    c. Approval of the application is based on a clinical trial of 144 eyes (74 primary and 70 secondary). Of all eyes treated, 134 were evaluated for effectiveness with 98.5% accountability at 3 months, 131 eyes with 97.0% accountability at 6 months, 118 eyes with 90.8% accountability at 9 months, and 27 eyes with 87.1% accountability at 12 months.

d. The studies found that of the 131 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 97.3% were corrected to 20/40 or better, and 66.2 % were corrected to 20/20 or better in 74 spherical hyperopia eyes; 93.0 % were corrected to 20/40 or better, and 56.1 % were corrected to 20/20 or better in 57 astigmatic hyperopia eyes.

e. The study showed that at the 6 month stability time point: there was no loss of ≥ 2 lines of best corrected vision that can be obtained with spectacles in either 63 astigmatic hyperopia eyes or 74 spherical hyperopia eyes; none of the 63 astigmatic hyperopia or 74 spherical hyperopic eyes had best spectacle corrected visual acuity (BSCVA) worse than 20/25. During the course of study, one in 63 eyes with astigmatic hyperopia lost >2 lines of BSCVA at 1 month, no eyes with spherical hyperopia lost >2 lines of BSCVA, and no eye had a BSCVA worse than 20/40.

f. The clinical trials showed that the following adverse events or complications occurred in at least 1% of the 144 eyes at any interval up to 6 months post-treatment: cells growing under the flap (2.1%); feeling of something in the eye (1.4%); double or ghost images (11.3%); and scratch on the surface of the eye (2.1%).

The following subjective symptoms rated "often or always" were increased in frequency in the effectiveness cohort at 6 months post-treatment on 131 eyes compared with pretreatment on 136 eyes: dryness (17% vs. 6%); blurry vision (10% vs. 7% ); fluctuation of vision (14% vs. 6%); halos (10% vs. 5%); double or ghost images (7% vs. 3%).

g. The safety and effectiveness of wavefront-guided LASIK surgery has ONLY been established with an optical zone 6.00 mm and an ablation zone of 9.00 mm.

h. Long term risks of wavefront-guided LASIK for hyperopic astigmatism beyond 12 months have not been studied.

i. The safety and effectiveness of STAR S4™ Excimer Laser System have NOT been established for wavefront-guided surgery in patients: whose WaveScan-measured pupil size is less than 5.00 mm; for treatments greater than 3.00 D of MRSE or with greater than 2.00D of astigmatism and for retreatment with CustomVue™ LASIK.

j. Although the WaveScan WaveFront® System measures the refractive error and wavefront aberrations of the human eyes, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher order aberrations through sixth order, in the clinical study for this PMA, the average higher order aberration did not decrease after CustomVue™ treatment.

k. Note that the complete name for this ophthalmic laser is "STAR S4™ Excimer Laser System for wavefront-guided laser assisted in situ keratomileusis (LASIK) treatments of hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 D". An acceptable alternate version of this official name is "wavefront-guided LASIK for correction of hyperopic astigmatism".

In addition to the postapproval requirements in the enclosure, you must report to FDA CDRH's Office of Compliance at the address below of any instances of device tampering or usage outside of the approved indications, and any excimer systems that were exported under an 801(e) order and are now back in the U.S.

OC/Division of Enforcement (HFZ-331)
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling affected by this supplement in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Dexiu Shi, Ph.D. at (301) 594-2018.

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Conditions of Approval